FEB 2 3 2000

K000364

Special 510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: February 2, 2000

2) Device name

Proprietary name: Accu-Chek™ Complete® Meter
Common name: whole blood glucose test system
Classification name: Glucose dehydrogenase, glucose

3) Predicate device

We claim substantial equivalence to the current legally marketed version of the same device.

4) Device Description

A modem that enables self-testers to send data from their Accu-Chek Complete blood glucose meter to their doctor, pharmacist, or other health care professional. The customer may send information to a computer or a facsimile (fax) machine. This data transfer takes place over regular telephone lines.

The Acculink™ Modem was designed to be convenient and easy to use. Installation is simple, the customer simply attaches their meter to the modem, connects the modem to the phone line, plugs in the AC Adapter, and is ready to transmit information.

The Acculink Modem kit includes the modem, an Accu-Chek Advantage Meter interface cable, an Accu-Chek Complete Meter interface cable, AC Adapter, phone cord, user's manual, and warranty card.

Continued on next page

Special 510(k) Summary, Continued

5) Intended use	The Accu-Chek Complete system is designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities. The Acculink Modem enables self-testers to send data from their Accu-Chek Complete blood glucose meter to their doctor, pharmacist, or other health care professional. The customer may send information to a computer or a facsimile (fax) machine. This data transfer takes place over regular telephone lines.
6) Comparison to predicate device	The Roche Diagnostics Accu-Chek Complete System is substantially equivalent to the current legally marketed version of the same device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 23 2000

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K000364
Trade Name: Accu-Chek™ Complete® Meter
Regulatory Class: II
Product Code: LFR
Dated: February 15, 2000
Received: February 16, 2000

Dear Mr. Flis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):
Device Name: Accu-Chek™ Complete® Meter

Indications for Use:

The Accu-Chek Complete system is designed for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.

The Acculink™ Modem enables self-testers to send data from their Accu-Chek Complete blood glucose meter to their doctor, pharmacist, or other health care professional. The customer may send information to a computer or a facsimile (fax) machine. This data transfer takes place over regular telephone lines.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020364

Prescription Use ___ (Per 21 CFR 801.109) OR Over-The-Counter Use ✓

(Optional Format 1-2-96)